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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/527,785 | 10/03/2005 | Marco Cattaruzza | DEBE:053US | 1068 |
| 32425 | 7590 | 10/06/2006 | EXAMINER | |
| FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 | | | WOLLENBERGER, LOUIS V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1635 | |

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 10/527,785 | Applicant(s) CATTARUZZA ET AL. | |
| | Examiner Louis V. Wollenberger | Art Unit 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the application/amendments

Applicants' preliminary amendment to the claims, filed 3/11/05, is acknowledged. With the amendment, claims 1–10 are pending and subject to restriction as follow.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1–3, drawn to a decoy oligonucleotide comprising the nucleic acid sequence according to SEQ ID NO:1 to 34, and to a method thereof for the prevention or therapy of a disease, as recited in claim 3. Election of this group requires the further election of a single nucleic acid sequence SEQ ID No. from claims 1 and 3 as explained below.

Group II, claim(s) 4–8, drawn to a method for the diagnosis of a C/T variance in the eNOS-gene. Election of this group requires the further election of a single oligonucleotide sequence SEQ ID No. from claims 6 and 7, as explained below.

Group III, claim(s) 9, drawn to a kit for the diagnosis of a C/T variance in the eNOS-gene.

Group IV, claim(s) 10, drawn to a DNA oligonucleotide comprising a nucleic acid sequence according to SEQ ID NO: 35 to 40 and 56 to 61. Election of this group requires the further election of a single nucleic acid sequence SEQ ID No. from claim 10.

The inventions listed as Groups I–IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a decoy oligonucleotide comprising the nucleic acid sequence according to SEQ ID NO:1–34, which is not present in any of the other groups.

Art Unit: 1635

The special technical feature of Groups II and III is a PCR-based method for the diagnosis of a C/T SNP in an eNOS gene, comprising a post-PCR restriction enzyme digestion step, which is not present in Groups I or IV. Furthermore, this cannot be a special technical feature under PCT Rule 13.2 because the technical feature is shown and/or obvious in view of the prior art (Nasreen et al. (2002) *Arterioscler Thromb. Vasc. Biol.* 22:605-610; Shimasaki et al. (1998) *J. Am. Coll. Cardiol.* 31:1506-1510), which teaches the combined use of polymerase chain reaction-restriction fragment length polymorphism analysis to detect missense mutations in the eNOS gene (Shimasaki et al., page 1507, for example), and the use of allele-specific PCR to detect the T-786C mutation in an eNOS gene in humans. Accordingly, there is a presumption of lack of novelty or inventive step in the main claim, and unity of invention is therefore lacking, *a posteriori*, between Groups II and III.

The special technical feature of Group IV is a DNA oligonucleotide comprising a nucleic acid sequence according to SEQ ID NO: 35 to 40 and 56 to 61, which is not present in any of the other groups.

Accordingly, unity of invention is lacking among Groups I-IV.

In addition, should applicants elect to prosecute any of Groups I, II, or IV, these groups are each subject to further restriction as follows.

Groups I, II, and IV each contain claims, claims 1, 3, 6, 7, and 10, that recite a plurality of different nucleic acid sequences.

The polynucleotides would be regarded as having the same or corresponding technical feature if the alternatives had a common property or activity, and shared a significant structural element that is essential to the common property or activity.

In the instant case, the description fails to disclose that all of the polynucleotides share a common property or activity. Moreover, while each sequence may share a common utility in the invention of which they are a part, the polynucleotides are not homologous to each other. Therefore, they fail to share a common structure i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since it is shared by all nucleic acid molecules. Therefore, the polynucleotide molecules do not share any significant structural element and cannot be considered as having the same or corresponding technical feature. Consequently, the group of polynucleotide molecules claimed does not meet the requirement of unity of invention (*a priori*) (See MPEP 803.02 and Annex B(f) of the PCT Administrative Instructions).

Accordingly, Applicants are required to elect one nucleic acid sequence, i.e., one SEQ ID NO:, for prosecution with the elected invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

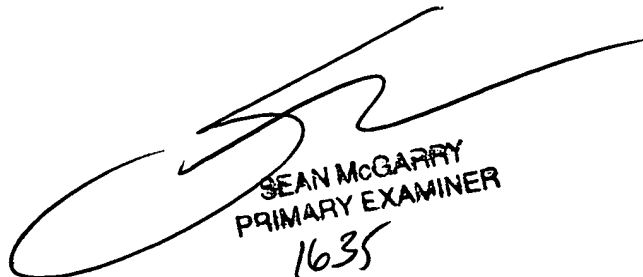
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

Art Unit: 1635

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571)272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louis Wollenberger
Examiner, Art Unit 1635
September 27, 2006



SEAN MCGARRY
PRIMARY EXAMINER
1635